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ESSAY

A Procedural Due Process Attack on FDA Regulations: Getting New Drugs to People with AIDS

Introduction

We hold these truths to be self-evident, that all Men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the Pursuit of Happiness—That to secure these Rights, Governments are instituted among Men, deriving their just Powers from the Consent of the Governed, that whenever any Form of Government becomes destructive of these Ends, it is the Right of the People to alter or abolish it.¹

“The strongest ills demand the speediest cure.”²

“Too late is the medicine prepared when the disease had gained strength by long delay.”³

“For want of timely care, Millions have died of medicable wounds.”⁴

AIDS, or Acquired Immune Deficiency Syndrome, is a disease caused by the Human Immunodeficiency Virus (HIV),⁵ which is a new strain in the family of retroviruses.⁶ AIDS devastates its human host by opening it to a variety of rare opportunistic infections, such as pneumonia and cancer.⁷ Because of medical science’s virtual ignorance in treat-

1. The Declaration of Independence para. 2 (U.S. 1776).

2. SOPHOCLES, *ANTIGONE* 1.1324 (c. 441 B.C.).

3. OVID, *REMEDIORUM AMORIS* 1.91 (c. 1 B.C.).

4. J. ARMSTRONG, *THE ART OF PRESERVING HEALTH*, Bk. iii, 1.519 (1744).

5. Grover, *AIDS: Keywords*, in *AIDS: CULTURAL ANALYSIS/CULTURAL ACTIVISM* 17, 19 (D. Crimp ed. 1988).

6. Treichler, *AIDS, Homophobia, and Biomedical Discourse: An Epidemic of Signification*, in *AIDS: CULTURAL ANALYSIS/CULTURAL ACTIVISM*, *supra* note 5, at 54 n.65.

7. DEP’T OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE & CENTERS FOR DISEASE CONTROL, *AMERICA RESPONDS TO AIDS, AIDS PREVENTION GUIDE, WHAT IS HIV INFECTION? AND WHAT IS AIDS?* (1989).

ing retroviruses, AIDS is a fatal disease. Western civilization has not faced the devastation of such a public health menace since the Black Plague of the Middle Ages.⁸ At the time of this writing, 115,158 Americans have been diagnosed with AIDS,⁹ 68,441 Americans have died,¹⁰ and over 1.5 million Americans have been exposed to HIV.¹¹

To date, no case of AIDS remission has been documented.¹² Medical researchers believe that persons infected with HIV will necessarily contract AIDS.¹³ Without expeditious development and dissemination of effective treatments and therapies, persons with AIDS may expect from eighteen months to two years of deteriorating health before the disease proves fatal.¹⁴

AIDS has presented America with a problem it has heretofore avoided: a fatal disease infecting the public in epidemic proportions. Treatments for AIDS are being developed by the private sector. Unfortunately, the speedy dissemination of new lifesaving drugs is being hampered by the Food and Drug Administration (FDA). The FDA requires that a new drug be approved according to a specified procedure. One requisite element of this procedure is the double blind placebo study.¹⁵ The drug approval procedure promulgated by the FDA can require up to twelve years to complete.¹⁶

Piqued at what they believe to be governmental foot dragging and governmental coercion of people with AIDS (PWAs)¹⁷ to wager their

8. Treichler, *supra* note 6, at 63.

9. Telephone interview with National AIDS Hotline (Jan. 19, 1990) (statistics as of Nov. 30, 1989); *see infra* note 176.

10. *Id.*

11. *Id.*

12. Grover, *supra* note 5, at 21; Treichler, *supra* note 6, at 32.

13. E. NICHOLS, MOBILIZING AGAINST AIDS (1989); Lipson, *A Crisis in Insurance*, in THE AIDS EPIDEMIC: PRIVATE RIGHTS AND THE PUBLIC INTEREST 285, 289 (P. O'Malley ed. 1989) (research suggests that AIDS may kill 99.9% of those who are exposed to HIV).

14. S. GREGORY & B. LEONARDO, CONQUERING AIDS NOW! 180 (1986); Comment, *The Right of Privacy in Choosing Medical Treatment: Should Terminally Ill Persons Have Access to Drugs Not Yet Approved by the Food and Drug Administration?*, 20 J. MARSHALL L. REV. 693 (1987).

15. In placebo-controlled drug studies, a placebo is given to one group of patients, while the drug being tested is given to another group. The results obtained in the two groups are then compared. *Glossary*, BETA, Nov. 1989, at 27 (BETA is a publication of the San Francisco AIDS Foundation). In double blind placebo studies, neither the investigator nor the patient knows who is getting which therapy; *see infra* note 38 and accompanying text.

16. J. BOHNE, T. CUNNINGHAM, J. ENGBRETSON, K. FORNATARO & M. HARRINGTON, TREATMENT DECISIONS 46-50 (1989) [hereinafter TREATMENT DECISIONS]. (Please note that this source was unavailable for verification at time of publication. Eds.).

17. At the second AIDS Forum, held in Denver in 1983, a group of men and women with AIDS and ARC (AIDS Related Complex) condemned the use of the words "AIDS victim" to describe their condition. In an act of self-acclaim, this group announced the moniker "Person with AIDS" or "PWA" as a more empowered naming of the condition. Grover, *supra* note 5, at 26-27.

lives, members of communities with a high risk of AIDS have organized actively to protest FDA policies and procedures by demonstrations at AIDS colloquia worldwide and by participating in civil disobedience at the national level.¹⁸ Such communities claim that the twelve year cycle which is common to complete the FDA approval method is effectively killing many PWAs who only have but a two year time frame in which to access drugs which may halt the progress of their disease.¹⁹ Additionally, AIDS activists are offended by the use of the double blind placebo method on humans. They claim the FDA has adopted a fundamentally inhumane testing methodology that is morally flawed by its "game of chance" character.²⁰

The Fifth Amendment guarantees that no person shall be deprived of life, liberty, or property without due process of law.²¹ This Essay will first argue that the government, through the FDA, deprives PWAs of their interests in life and liberty by precluding them from obtaining life-extending drugs or by coercing them to participate in placebo studies. Second, this Essay will propose additional, substitute procedures that would both safeguard PWAs' interests in life and liberty and streamline the drug testing process. Third, this Essay will illustrate how the federal government's interest in protecting the public from unsafe or ineffective drugs would remain qualitatively unaffected by such alternative procedures. In conclusion, this Essay will recommend the abandonment of the strict double blind placebo method and the substitution of a far more humane and ethical procedure for assuring the safety and efficacy of new drugs.

I. Short History of AIDS in the United States

In 1983, Robert Gallo in the United States and Luc Montagnier in France each isolated the retrovirus responsible for the immune dysfunction presented by PWAs.²² While the virus was known as HTLV-III (Human T-cell Leukemia/Lymphoma Virus III) in the United States and LAV (Lymphadenopathy-Associated Virus) in France, the virus in each case was the same.²³ Finally, in 1986, a subcommittee of the International Committee on the Taxonomy of Viruses agreed to call the new retrovirus HIV or Human Immunodeficiency Virus.²⁴

18. Bordowitz, *Picture a Coalition*, in AIDS: CULTURAL ANALYSIS/CULTURAL ACTIVISM, *supra* note 5, at 183.

19. TREATMENT DECISIONS, *supra* note 16, at 183.

20. Bordowitz, *supra* note 18, at 183; Letter to the Editor from Jesse C. Dobson, ACT-UP/ San Francisco, San Francisco Bay Times, Dec. 1989, at 3, col 2.

21. U.S. CONST. amend. V.

22. E. NICHOLS, *supra* note 13, at 95-102.

23. *Id.*

24. *Id.* at 105.

Until 1985, AIDS remained largely identified as a "gay disease." Ironically, when Rock Hudson, screen idol of the 1950s, revealed his AIDS diagnosis, mainstream America awakened to the possibility that the disease could infect individuals beyond the high risk community of urban gay men.²⁵ Beginning in 1986, dissemination of safer sex literature began in mainstream communities at the recommendation of Surgeon General C. Everett Koop.²⁶

By November 1989, 115,158 persons in the United States were diagnosed with AIDS. Of those persons, 68,441 died due to advanced opportunistic infection.²⁷ AZT, or azidothymidine, remains the only FDA-approved treatment for HIV infection.²⁸ While helpful in prolonging life, AZT has not proven to be extraordinarily beneficial.²⁹ Although safer sex literature has been sent to every household in America, and newer therapies are being discovered, the number of people who will be diagnosed with AIDS is expected to double by the beginning of 1992.³⁰

II. Overview of the FDA's New Drug Approval Process

The Federal Food, Drug, and Cosmetic Act (FDCA) requires that a new drug be proven safe and effective before it can be sold to the public.³¹ In compliance with the FDCA, the FDA has promulgated regulations outlining the procedures for proving the safety and efficacy of a new drug.

To introduce into interstate commerce a new drug not yet proven safe and effective, the drug's proponent must file with the FDA a signed "Notice of Claimed Investigational Exemption for a New Drug" (IND).³² Before an IND application is approved, the drug company must produce sufficient evidence to show that the drug is reasonably safe for introduction into humans for experimental purposes. Furthermore, the FDA requires the sponsor of the drug to organize and accept ultimate responsibility for meeting all the requirements of the IND process.³³

New drug investigations must follow a three-tiered approach.³⁴

25. S. GREGORY & B. LEONARDO, *supra* note 14, at 171; Treichler, *supra* note 6, at 34, 43.

26. Gray, *The AIDS Epidemic: A Prism Distorting Social and Legal Principles*, in *THE AIDS EPIDEMIC: PRIVATE RIGHTS AND THE PUBLIC INTEREST*, *supra* note 13, at 227, 247 n. 53; telephone interview with National AIDS Hotline (Jan. 19, 1990).

27. Telephone interview with National AIDS Hotline (Jan. 19, 1990).

28. E. NICHOLS, *supra* note 13, at 210.

29. See *infra* notes 41-68 and accompanying text.

30. Telephone interview with National AIDS Hotline (Jan. 19, 1990).

31. 21 U.S.C. §§ 355(d) (1988). The FDCA is codified at 21 U.S.C. §§ 301-93 (1988).

32. 21 C.F.R. § 312.23 (1987).

33. *Id.* § 312.50.

34. *Id.* § 312.21; TREATMENT DECISIONS, *supra* note 16, at 49.

Phases I and II "determine the clinical pharmacology of a new drug."³⁵ In other words, these stages are designed to test first for the drug's toxicity, preferred route of administration, safe dosage range, and effect on people with a specific disease. Although data on efficacy is also collected, it is not the focus of either phase I or phase II. Finally, in phase III, a new drug is clinically tested to assess its ultimate safety and efficacy.³⁶

The testing method used during phases II and III of the IND process is called a double blind placebo study.³⁷ In such a study, neither the doctor nor the patient is told whether the patient is using the experimental drug or a placebo.³⁸ The double blind test is advocated by the FDA to ensure scientific results with the least amount of uncontrolled variables.³⁹ Double blind studies theoretically protect against any bias a researcher or a participant may have in favor of the drug.⁴⁰

III. Procedural Due Process and the *Mathews v. Eldridge* Factors

The Fifth Amendment assures each American that "no person shall be . . . deprived of life, liberty, or property without due process of law."⁴¹ The meaning of "due process" has eluded scholars and judges alike. The concept has been subjected to piecemeal academic and judicial interpretation.⁴² The United States Supreme Court has consistently taken an instrumental approach in determining what procedures are due.⁴³ This approach accords little value to individual dignity, emphasizing the minimization of the possibility of factual error in the application of substantive rules.⁴⁴ The Court believes that this approach accounts for specific factual contexts, applying due process safeguards fairly to the particulars of each situation.⁴⁵ Thus, due process safeguards that are applicable to experimental therapies in the AIDS context should be tailored to the exigencies of this health crisis.

The definitive interpretation of procedural due process in the admin-

35. Comment, *supra* note 14, at 700.

36. *Id.*; see TREATMENT DECISIONS, *supra* note 16.

37. 21 C.F.R. § 314.126(b)(2)(i) (1987).

38. TREATMENT DECISIONS, *supra* note 16, at 49; Comment, *supra* note 14, at 700.

39. TREATMENT DECISIONS, *supra* note 16, at 49.

40. *Id.*

41. U.S. CONST. amend. V.

42. Lecture by W. Ray Forrester, Professor of Constitutional Law, Hastings College of the Law, San Francisco, Cal. (Nov. 3, 1989).

43. L. TRIBE, AMERICAN CONSTITUTIONAL LAW 714 (2d ed. 1988).

44. *Id.*

45. Professor Tribe cites three cases in which the Supreme Court has noted the relevance of specific factual contexts in determining "what process is due": *Morrissey v. Brewer*, 408 U.S. 471, 481 (1972); *Cafeteria and Restaurant Workers Union v. McElroy*, 367 U.S. 886, 895 (1961); *Hannah v. Larche*, 363 U.S. 420, 442 (1960). See L. TRIBE, *supra* note 43, at 714.

istrative context is *Mathews*.⁴⁶ In *Mathews*, Justice Powell, writing for the majority, noted that "'due process,' unlike some legal rules, is not a technical conception with a fixed content unrelated to time, place and circumstances."⁴⁷ He continued: "Accordingly, resolution of the issue whether the administrative procedures provided here are constitutionally sufficient requires analysis of the governmental and private interests that are affected."⁴⁸ Thus, to identify the specific dictates of due process, one must consider the following three factors:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.⁴⁹

In *Mathews v. Eldridge*, Powell's procedural due process formula serves "a crude sort of social welfare function."⁵⁰ He weighs and balances the private interest that is affected against the public interest as stated by the government. Curiously, the weighing and balancing Powell promulgates contrasts sharply with the Court's standard mode of deciding whether a procedural due process right is at issue: "as long as a property [or liberty] deprivation is not *de minimis*, its gravity is irrelevant to the question of whether account must be taken of the due process clause."⁵¹ This incongruence indicates that the *Mathews* Court created an implicit presumption of constitutionality for procedural safeguards provided by the government.⁵²

This presumption dilutes the constitutional protection accorded persons under the Due Process Clause. By presuming a procedure is constitutional, the Court abdicates its responsibility to protect individual rights.⁵³ During the Constitutional Convention, the Framers decided "to safeguard certain rights and values, those considered fundamental in a free society and yet unusually vulnerable to the risk of denial by the ma-

46. 424 U.S. 319 (1976). In *Mathews*, the Court considered whether a person whose social security disability benefits had been terminated by the Department of Health, Education, and Welfare (HEW) had been afforded due process. Holding that the HEW procedures did comport with due process, the Court developed the balancing-of-factors test which remains the hallmark of due process in the administrative procedure context. See *id.* at 335.

47. *Id.* at 334 (quoting *Cafeteria and Restaurant Workers Union*, 367 U.S. at 895).

48. *Id.*

49. *Id.* at 335.

50. L. TRIBE, *supra* note 43, at 715.

51. *Id.* (citing *Goss v. Lopez*, 419 U.S. 565, 576 (1975)).

52. "[S]ubstantial weight must be given to the good faith judgment of the individuals charged by Congress with the administration of the social welfare programs that the procedures they have provided assure fair consideration of the entitlement claims of individuals." *Mathews*, 424 U.S. at 349; see also L. TRIBE, *supra* note 43, at 717.

53. L. TRIBE, *supra* note 43, at 718.

jority.”⁵⁴ Protecting such “core” rights precludes “balancing” the general interests of the majority against those of the individual.⁵⁵ “The proper role of [the Supreme Court] in this context is to define and protect those substantive and procedural rights that may not receive their due respect in the political [majoritarian] process.”⁵⁶ This role of the Court—to provide additional protection—justifies judicial review of administrative procedures to ensure their compliance with constitutional norms.⁵⁷

Although Justice Powell’s balancing-of-factors in *Mathews v. Eldridge* belies the theoretical function of the Supreme Court in the American constitutional process, its practical effect is to protect most administrative regulations from constitutional challenge. Thus, to effectuate a change in FDA drug approval methods, one is required to surmount the presumption of constitutionality established in *Mathews*. This Essay attempts to rebut this presumption as it applies to the FDA’s approval of new AIDS drugs.

A. Factor One: Life and Liberty Are the Private Interests Affected by Use of Double Blind Placebo Method

The first factor to be established under a *Mathews v. Eldridge* challenge is the existence of a private interest that will be detrimentally affected by official governmental action.⁵⁸

The FDA’s procedure for approving new drugs constitutes an official government action. Congress requires that new drugs that are to be marketed and sold in interstate commerce be approved by the FDA according to outlined administrative regulations.⁵⁹ These regulations mandate the use of double blind placebo studies to establish the drug’s efficacy.⁶⁰ All new drugs are subject to these regulations, and none are exempted from them.⁶¹ All new drugs are subject to the same standards, regardless of whether they are new headache medications or treatments for an incurable disease.⁶²

54. *Id.*

55. *Id.*

56. *Id.*

57. *Id.*

58. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976). The private interest impacted by official action must fall categorically within life, liberty, or property to trigger the protections of the Due Process Clause. *Id.* at 332.

59. 21 U.S.C. § 355 (1985).

60. See *supra* note 15 and accompanying text.

61. TREATMENT DECISIONS, *supra* note 16, at 53.

62. *Id.*

1. *The Private Interest of Life*

The FDA's use of the double blind placebo method to approve new drugs deprives PWAs of two private interests, one of which is a private interest in life. AIDS is caused by a strain of retrovirus for which there is no cure or reliable therapy.⁶³ Thus far, over 60,000 lives have been lost to the scourge of AIDS.⁶⁴ AZT, the only approved drug or therapy for HIV infection,⁶⁵ cannot be used by many PWAs because of its serious toxic side effects, such as bone marrow suppression, anemia, neutropenia, leukopenia, nausea, rash, and confusion.⁶⁶ Additionally, AZT is incompatible with other anti-viral drugs, such as Ganciclovir, which is prescribed for persons suffering from CMV retinitis,⁶⁷ an opportunistic infection attacking the retina and causing blindness. Thus, AZT is unavailable to many people needing these other treatment modalities. Scientists believe AZT loses its effectiveness against HIV after only six months to a year and a half for those who take the drug.⁶⁸

Unlike the availability and effectiveness of radiation and chemotherapy for cancer patients, no lifesaving treatments exist for AIDS. Because of this dearth of lifesaving therapies and the limited applicability of AZT, most PWAs remain untreated for HIV. Thus, the rationale adopted by the Court in *United States v. Rutherford*⁶⁹ is inapplicable in the AIDS context. *Rutherford* is the leading Supreme Court case in the area of experimental drugs. The *Rutherford* Court refused to exempt Laetrile from FDA approval process because it feared cancer patients would rely upon unproven Laetrile therapy in lieu of conventional lifesaving treatments. Because the PWA has few, if any, possible treatments for his or her disease, reliance upon *Rutherford* in the AIDS drug context would be both injudicious and premature.

The only possibility for life rests with private development of new drugs. All drugs are subjected to double blind placebo studies. Although FDA regulations are not directly responsible for an individual's HIV infection, they contribute indirectly to the progress of the disease. Double blind placebo studies are lengthy, narrow, frequently discriminatory, and prone to bias.⁷⁰ They exacerbate the fatal quality of AIDS because they alone allow access to treatment that may extend life.

63. See *supra* notes 12-14 and accompanying text.

64. See *supra* note 10. In 1989, the Centers for Disease Control (CDC) predicted that AIDS would increase to be the third or fourth leading cause of premature death in the United States by 1991. E. NICHOLS, *supra* note 13, at 20.

65. E. NICHOLS, *supra* note 13, at 210.

66. TREATMENT DECISIONS, *supra* note 16, at 7-8; Baker, *AZT Update*, BETA, Nov. 1989, at 22-23.

67. Thalsen, *Brief Notes*, BETA, Nov. 1989, at 28.

68. Baker, *supra* note 66, at 12.

69. 442 U.S. 544 (1979).

70. See TREATMENT DECISIONS, *supra* note 16, at 49, 58-63.

When participation in double blind placebo studies is denied due to sex, race, age, health condition, or economic support,⁷¹ the possibility of extended life is also denied to those individuals. Double blind placebo studies limit participation to a numbered few and deny the potential for life to all others who are not allowed to participate. Generations of PWAs will die while double blind placebo studies, which require up to twelve years before sufficient data are generated and compiled, await FDA approval.

Professor Laurence Tribe affirms the notion that not only official action, but also official inaction, may impact one's private interest in life:

Emerging notions that government has an affirmative obligation somehow to provide at least a minimally decent subsistence with respect to the most basic human needs, subject to all of the familiar difficulties with judicial enforcement of affirmative duties, thus fit quite naturally into a conception of bodily integrity in which a governmental omission can be as deadly as the most pointed of governmental acts.⁷²

Official action via FDA drug approval regulations profoundly impacts a PWA's interest in life. A PWA may lose his or her life as a result of the FDA interposing itself between the helpful drug and the desperate untreated patient. Ovid long ago realized the importance of the early treatment of disease: "Too late is the medicine prepared when the disease had gained strength by long delay."⁷³

To argue that due process need not be afforded to PWAs because the governmental action is not directly responsible for HIV infection, ignores the direct involvement of the FDA in the onslaught of AIDS. In utilizing the double blind placebo method, the FDA delays dissemination of helpful drugs and therapies to sick people.⁷⁴

In *Estelle v. Gamble*,⁷⁵ a case concerning the availability of medical care to prisoners, Justice Stevens correctly insisted that "[w]hether the

71. *Id.*; Long, Enrollment and Demographic Representation In Clinical Trials: Problems To Be Solved (Dec. 5, 1989) (written testimony presented to National Institute of Health AIDS Program Study, Committee of the Institute of Medicine, The National Academy of Science).

72. L. TRIBE, *supra* note 43, at 1336.

73. OVID, REMEDIORUM AMORIS 1.91 (c. 1 B.C.).

74. But physical violation need not be of the "rape, murder, fire and sword" variety characterized by the "sudden forceful, and perhaps unexpected infliction of painful physical injury upon an unwilling victim. . . . Where muggings and violent demonstrations are the fear and the theorists speak for the fearful, vigorous direct actions will seem the most important features of violence. Where the streets are quiet, but people who could be saved are left to die of neglect or cold or hunger, or are crippled or killed by their living or working conditions, a different group of people may suffer, and other theorists may see their suffering as attributable to human agency, and so class it as part of man's violence to man."

L. TRIBE, *supra* note 43, at 1335 (quoting Harris, *The Marxist Conception of Violence*, 3 PHIL. & PUB. AFF. 192, 215, 219 (1974)).

75. 429 U.S. 97 (1976).

[poor] conditions [of the prison] were the product of design, negligence, or mere poverty, they were cruel and inhuman."⁷⁶ He concluded that governmental indifference to a prisoner's medical needs violates the Eighth and Fourteenth Amendments.⁷⁷ Likewise, Justice Brennan, dissenting in *DeShaney v. Winnebago County Department of Social Services*,⁷⁸ noted that "if a State cuts off private sources of aid itself, it cannot wash its hands of the harm that results from its inaction."⁷⁹ Thus, certain Supreme Court Justices have acknowledged that governmental inaction can wrongfully deprive people of their life and liberty by denying them the protection of due process.

2. *The Private Interest of Liberty*

The second private interest that is affected by the FDA's methods for approving drugs is a liberty interest. PWAs have a fundamental right to liberty, derived from the right of privacy, to choose for themselves treatment with unapproved experimental drugs. This Essay will not explore the PWA's right to privacy in choosing medical treatment. This proposition has been argued persuasively elsewhere.⁸⁰ I only posit that PWAs do have this right. Almost one hundred years ago, the Court opined that "[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."⁸¹ The Court concluded that "[t]he right to one's person may be said to be a right of complete immunity to be let alone."⁸² The FDA's interception of new AIDS drugs interferes with the possession and control of the PWA's own body. The PWA's right to his or her person is the right of access to helpful therapies and drugs.

Professor Tribe perceives one's right to personhood, or the right to one's own self-realization, as incapable of absolute protection from all interference by the government.⁸³ He notes, however, that where one's personhood confronts the strong arm of governmental coercion or neglect, it manifests itself as a fundamental right worthy of constitutional protection.⁸⁴ In the AIDS context, the FDA drug approval procedure

76. *Id.* at 116-17 (Stevens, J., dissenting).

77. *Id.*

78. 489 U.S. 189 (1989).

79. *Id.* at 207 (Brennan, J., dissenting).

80. See Comment, *supra* note 14; see also *State Bd. of Medical Examiners v. Rogers*, 387 So. 2d 937 (Fla. 1980) (right of physician to exercise professional judgment to administer non-hazardous experimental drug).

81. *Union Pacific Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

82. *Id.*

83. L. TRIBE, *supra* note 43, at 1305.

84. *Id.* at 1305-06.

functions as a strong arm foreclosing PWAs' free exercise of what they will do with their own bodies. The FDA coerces PWAs to participate in placebo trials, jeopardizing the lives of participants who receive placebos. The FDA also neglects PWAs by denying them the new drug they need to survive. Thus, the FDA action gives rise to a fundamental right worthy of constitutional protection—namely, procedural due process. This right emanates from a PWA's right to both liberty and personhood.

B. Factor Two: The Double Blind Placebo Method Erroneously Deprives PWAs of Their Private Interests in Life and Liberty and the Value of Substitute Procedural Safeguards is Great

The second factor to be considered in a *Mathews v. Eldridge* challenge is "the risk of an erroneous deprivation of [the private] interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards."⁸⁵

1. The Risk of an Erroneous Deprivation of Life and Liberty

The FDA's use of the double blind placebo method poses a high risk for the erroneous deprivation of a PWA's life. Phases II and III of a new drug investigation constitute a protracted procedure requiring up to twelve years to complete.⁸⁶ Most of the time required for new drug approval is primarily dedicated to the double blind placebo study.⁸⁷ If an approval procedure consumes an average of twelve years, at least six "generations" of PWAs die before access to the helpful drug is allowed.⁸⁸ As simple mathematics establishes, hundreds of thousands of lives could be affected over the course of twelve years.⁸⁹ Phase I studies collect data regarding efficacy, while also establishing the level of toxicity. Therefore, while the double blind placebo study is being administered to a select group of participants, the drug is known to have certain palliative quali-

85. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

86. See *supra* note 16 and accompanying text.

87. See *supra* note 15 and accompanying text.

88. The projected life expectancy upon a diagnosis with AIDS is eighteen months to two years. Thus, in twelve years, six "generations" of people will be diagnosed and will die of AIDS. This is a conservative estimate, assuming no one generation will be diagnosed until the previous generation has died.

89. In two years, 200,000 additional people will have died from AIDS. If AIDS continues as it did in the 1980s, the infection rate will grow exponentially. Obviously, this growth rate would project well over one million people dead by 2002. See Letter from Joel Wiesman, M.D., Chairman, American Foundation for AIDS Research (AMFAR) to AMFAR supporters (January 1990); see also J. JAMES, AIDS TREATMENT NEWS 341 (1989) ("Barring a miracle, hundreds of thousands of people in the United States alone are expected to die of AIDS over the next several years—and the Federally-controlled research establishment as it is currently operating will have little impact on this catastrophe.").

ties. Yet, it is not given to fatally afflicted people who will certainly die without it.

Although the double blind placebo method is reliable, it requires too much valuable time and is overly extensive. The FDCA only requires a reasonable method for testing new drugs.⁹⁰ The double blind placebo method is extreme and beyond the congressional mandate for reasonableness.⁹¹ Because the FDA has opted for scientific procedures of the strictest order, it has established criteria "often harmful to the people in the studies" as well as to people afflicted with AIDS outside of the studies.⁹² This method, far in excess of that needed to establish reasonable safety and efficacy, is not questioned by "mainstream science which accepts orthodox trial methodology as a sacred absolute."⁹³ As a result, the fastidious procedures of phase II and phase III testing prove deadly when thousands are waiting for helpful treatments. Thus, the exigency of AIDS requires the use of more expedient methods to test for efficacy.

Mainstream science should begin to question whether drugs could be tested more rapidly using alternative methodologies. The fruit of such reactive curiosity would be the abandonment of the double blind placebo method in favor of a more reasonable methodology to be used in these circumstances.

The FDA's use of the double blind placebo method also erroneously deprives a PWA of liberty. "[F]undamental in American jurisprudence [is the notion] that every human being of adult years and sound mind has a right to determine what shall be done to his own body."⁹⁴ Under current FDA regulations, PWAs unable to take AZT and without any other means with which to attack the HIV must await the completion of double blind placebo studies before they may be able to receive a drug that has already proven to be somewhat effective. Ironically, the government seeks to protect the PWA by engaging the new drug in a double blind placebo study.⁹⁵ Common sense evinces the absurdity that a person with AIDS will be dead long before the FDA allows a new drug to be dispensed at all. The FDA will have acted to protect PWAs from deleterious drugs while HIV ravages their bodies.

90. 21 U.S.C. § 355(d)(1) (1985).

91. TREATMENT DECISIONS, *supra* note 16, at 53-54.

92. *Id.*

93. *Id.*

94. Suenram v. Society of Valley Hospital, 155 N.J. Super. 593, 601-02, 383 A.2d 143, 148 (1977) (quoting Canterbury v. Spence, 464 F.2d 772, 780 (D.C. Cir. 1972)).

95. See Toole v. Richardson-Merrell Inc., 251 Cal. App. 2d 689, 704, 60 Cal. Rptr. 398, 409 (1967). But see J. JAMES, *supra* note 89, at 352 (In 1988, Vice-President George Bush recommended that for life-threatening disease, phase III testing be eliminated for helpful drugs. "This phase takes the longest, yet it contributes the least, since the great majority of drugs which begin phase III are eventually approved, . . . [and they] have already been proved safe in phase I, and probably effective in phase II.").

Analogous to the government protecting its citizens from dangerous drugs is a state social worker's role in protecting an abused child. The United States Supreme Court held in 1989 that no due process claim arose in a case where a social worker did not extricate an abused child from his abusive father's care.⁹⁶ This result begs the question of whether a due process claim arises when a government agent takes the child into state custody. Two Supreme Court rulings, *Youngberg v. Romeo*⁹⁷ and *Estelle v. Gamble*,⁹⁸ answer this question affirmatively. The *Romeo* Court held that an involuntarily committed retarded person has a due process liberty interest that compels the state "to provide minimally adequate or reasonable training to ensure safety and freedom from undue restraint."⁹⁹ In *Gamble*, the Court held that broad and idealistic concepts of human dignity, civilized standards, and decency establish the government's obligation to care for a prisoner who cannot, by reason of the deprivation of his liberty, care for himself.¹⁰⁰

The government role in these cases is clearly analogous to the role of the FDA in drug approval: the issue is not whether FDA approval regulations constitute a due process violation per se, but whether the FDA's use of the double blind placebo method in approving new drugs causes a loss of life and liberty and thus violates due process.

The Court in *DeShaney* noted that due process is implicated when "the State by the affirmative exercise of its power so restrains an individual's liberty that it renders him unable to care for himself, and at the same time fails to provide for his basic human needs—e.g., food, clothing, shelter, medical care, and reasonable safety"¹⁰¹ The *DeShaney* Court continued:

In the . . . due process analysis, it is the State's affirmative act of restraining the individual's freedom to act on his own behalf—through incarceration, institutionalization, or other similar restraint of personal liberty—which is the "deprivation of liberty" triggering the protections of the Due Process Clause, not its failure to act to protect his liberty interests against harms inflicted by other means.¹⁰²

In the AIDS drug approval context, the federal government takes PWAs into its own protective custody by disallowing them access to helpful drugs. Drug approval protects PWAs from deleterious drugs.¹⁰³ To dis-

96. *DeShaney v. Winnebago County Dep't of Social Servs.*, 109 S. Ct. 998 (1989).

97. 457 U.S. 307 (1982).

98. 429 U.S. 97 (1976).

99. *Romeo*, 457 U.S. at 319.

100. *Gamble*, 429 U.S. at 102-04.

101. *DeShaney v. Winnebago County Dept. of Social Servs.*, 109 S. Ct. 998, 1005-06 (1989).

102. *Id.* at 1006.

103. See *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398, 409 (1967).

allow PWAs the freedom to act on their own behalf¹⁰⁴ in choosing helpful drugs for their treatment is to deprive them of liberty. This deprivation "trigger[s] the protections of the Due Process Clause."¹⁰⁵

Justice Brennan, dissenting in *DeShaney*, agreed: "I would read [*Romeo*] and [*Gamble*] to stand for the much more generous proposition that, if a State cuts off private sources of aid and then refuses aid itself, it cannot wash its hands of the harm that results from its inaction."¹⁰⁶ He continued: "We have acknowledged that a State's actions—such as the monopolization of a particular path of relief—may impose upon the State certain positive duties. . . . [A] State may be found complicit in an injury even if it did not create the situation that caused the harm."¹⁰⁷

Following Brennan's reasoning and the Court's holding in *DeShaney*, one may persuasively argue that the government's direct intervention in the dissemination of new drugs is a "monopolization of a particular path of relief"¹⁰⁸ that makes it "complicit"¹⁰⁹ in the onslaught of AIDS. This monopolization is custodial insofar as the approval and regulation of AIDS drugs seek to protect PWAs from unapproved drugs. Unapproved drugs are kept in the FDA's custody. Thus, the only relief is kept in the government's custody. The custodial nature of the government's action through the FDA triggers due process protections under *Romeo* and *Gamble* because the PWA is deprived of governmental relief and is cut off from seeking other relief.

The FDA deprives PWAs of their fundamental liberty interest—the right to determine what shall be done with their own bodies—and substitutes a system of chance and luck in its place. Double blind placebo studies are exercises in wagering. Proponents of double blind placebo studies believe that participation in a new drug study is consensual, informed, and noncoerced.¹¹⁰ They conclude that PWAs do exercise their right to choose what shall be done with their bodies when they participate in a double blind placebo study. Although participation in a double blind placebo study requires the informed consent of the patient,¹¹¹ this consent by a person with AIDS is only ostensibly voluntary. Much like

104. *DeShaney*, 109 S. Ct. at 1006.

105. *Id.*

106. *Id.* at 1009 (Brennan, J., dissenting).

107. *Id.*

108. *Id.*

109. *Id.*

110. TREATMENT DECISIONS, *supra* note 16, at 58.

111. *Id.* But see Grodin, Kaminow & Sassower, *Ethical Issues in AIDS Research*, in THE AIDS EPIDEMIC: PRIVATE RIGHTS AND THE PUBLIC INTEREST, *supra* note 13, at 222 ("[w]hen research involves a dying patient whose body has been ravaged by a continuous series of recurring infections and the patient is given a glimmer of relief, the consent can hardly be considered freely given by a nonvulnerable person"); J. JAMES, *supra* note 89, at 77 (after AZT had proved effective in the treatment of AIDS, researchers denied AZT to 10,000 people in order to force several hundred participants to participate in placebo trials).

the fable of the lady and the tiger, in which a prisoner was forced to choose between two doors behind which he would either encounter life with a beautiful woman or death by the attack of a tiger, the choice given to PWAs is to participate in a game of chance or die. When a PWA does participate, the "choice" is one that may or may not assure access to the drug. Under these conditions, access, and thus life, is ultimately determined by luck.

Modern standards of morality and humanity require the abandonment of the double blind placebo method. The double blind placebo method requires that PWAs wager their lives to gain access to a helpful drug. During phases I and II, early signs of a drug's efficacy are determined while tests for toxicity and safety are run.¹¹² AZT is one such drug that proved beneficial to PWAs during phases I and II.¹¹³ Because beneficial drugs may reveal themselves during phases I and II, use of the double blind placebo method to approve such drugs is simply excessive when many PWAs could clearly benefit from their use. Asking PWAs to bet their lives that they do not get a sugar pill bears no reasonable relationship to the protection of the public's health and welfare where toxicity has already been established, efficacy has been proven preliminarily, and the public health has been safeguarded effectively. Thus, the double blind placebo method functions as "arbitrary governmental action"¹¹⁴ that gambles with a person's life.

Professor Tribe notes that American jurisprudence refuses to countenance a rule of law that requires a sacrifice by one for the benefit of many:

[T]hat one person's two good eyes, distributed to two blind neighbors, might yield a net increase in happiness on the theory that one blind person will experience less misery than two, cannot justify a governmental decision to compel the exchange. Even if one does not believe that human sacrifice is never justifiable, courts have long recognized the wisdom of acting *as though* persons could never be used as means to the ends of others, knowing that any clear departure from that ideal could spell the beginning of a disastrous slide.¹¹⁵

Thus, double blind placebo studies must yield to alternatives that do not require that PWAs sacrifice their life or liberty for the common good.

112. 21 C.F.R. § 312.21 (1987).

113. TREATMENT DECISIONS, *supra* note 16, at 31.

114. See *Youngberg v. Romero*, 457 U.S. 307, 316 (citing *Greenholtz v. Nebraska Penal Inmates*, 442 U.S. 1, 18 (1979)); cf. *DeVito v. HEM, Inc.*, 705 F. Supp. 1076, 1077 (M.D. Pa. 1988) (A person with ARC participated in a double blind study in which he received a placebo. He soon thereafter progressed to AIDS. The federal district court noted that his progression to AIDS was "unfortunate.").

115. L. TRIBE, *supra* note 43, at 1334-35 (emphasis in original).

The FDA's argument that a PWA has no right to privacy to decide which drugs to use undermines the federal government's claim that there is no government deprivation of liberty. The FDA may argue that the dangers of unapproved drugs require that the government maintain the integrity of the pharmaceutical drug industry.¹¹⁶ Consequently, this argument by the FDA substantiates the claim of PWAs that their right to privacy—the right to decide which drugs to use—exists and is deprived insofar as the government acts to protect its citizens from the dangers of unapproved drugs.

2. *Value of Additional or Substitute Safeguards*

Health care professionals who are involved in the testing of new drugs for AIDS treatment believe alternatives to double blind placebo studies could assure the protection of the public health and streamline the testing process.

a. Crossover Method

Health care professionals have suggested a modified application of the double blind placebo method to minimize the luck element inherent in a double blind study and enhance the collection of reliable data.¹¹⁷ This modification is called the crossover method.¹¹⁸ The crossover method first splits the participant pool in half. One half of the pool receives the drug while the other half receives a placebo.¹¹⁹ Midway through the study, the half receiving the placebo is switched to the drug and vice versa. Thus, at the conclusion of a study using the crossover method, all the participants in the pool have received both a placebo and the drug.¹²⁰

Under the crossover method, the study lasts for the same duration as a double blind study. The crossover method displaces the "lady and tiger" element inherent in a double blind placebo study by distributing the drug to all participants. The crossover method has great potential as an alternative to double blind studies because the data collected from a study using the crossover method is reasonably reliable in comparison to that collected from a double blind study.¹²¹

b. Treatment IND Method

The Treatment IND is a procedure for moving promising drugs

116. See, e.g., *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609 (1973).

117. Interview with Ed Freeman, nurse practitioner who conducts studies for the HIV Institute at Davies Medical Center, San Francisco, Cal. (Dec. 11, 1989).

118. *Id.*

119. *Id.*

120. *Id.*

121. *Id.*

through the FDA pipeline at an accelerated pace.¹²² In order for a drug to be considered for distribution through this program, it must have completed phase I testing and be supported by evidence of efficacy with no extreme toxicities.¹²³ Additionally, the drug must be in the process of being tested as an agent against a severe or life threatening illness, such as AIDS.¹²⁴ AZT was released in a modified Treatment IND program in 1987.¹²⁵

Drugs are not usually considered for Treatment IND status until mid to late phase II testing.¹²⁶ In a Treatment IND protocol, the individual's private physician registers with the manufacturer, obtains and dispenses the drug, and agrees to collect data and meet other requirements imposed by the manufacturer.¹²⁷ These requirements, as well as the number of participants, will vary for each drug accepted into the program. It must be stressed that policies and procedures pertaining to Treatment IND are still in flux. The program is subject to change, and the future of Treatment IND will depend largely on how well it works with the approval of the drug dideozinosine (ddI).¹²⁸

The drug ddI is one of a group of promising anti-HIV drugs called nucleoside analogues.¹²⁹ Like AZT, it works by inhibiting the replication of HIV in the cell, thereby reducing the rate at which cells become infected with the virus.¹³⁰ Treatment IND protocol makes ddI available to PWAs and people with ARC who have developed an intolerance to AZT.¹³¹ Participants must either have a diagnosis of AIDS as defined by the Centers for Disease Control (CDC) or be HIV positive and symptomatic with a T-helper cell count of less than 200.¹³²

122. See Roy, *Parallel Track and Treatment IND*, BETA, Nov. 1989, at 5; see also E. NICHOLS, *supra* note 13, at 199-200.

123. Roy, *supra* note 122, at 5.

124. *Id.*

125. *Id.*; see Grodin, Kaminow & Sassower, *supra* note 111, at 219 ("AZT has thus proven to be a paradigm for a reasonable approach to drug testing in AIDS.").

126. Roy, *supra* note 122, at 5.

127. *Id.*

128. *Id.*

129. Hafs, *ddI*, BETA, Nov. 1989, at 1.

130. *Id.*

131. *Id.* at 3. AZT intolerance is defined by any one of several adverse reactions, including the following: (1) a drop in hemoglobin of at least two grams a month; (2) a drop in the neutrophil count to less than 750 cells per mm; (3) severe nausea and/or vomiting; (4) severe headaches that do not respond to analgesics; and (5) declining muscle strength, such as inability to climb stairs. *Id.*

132. See *id.* at 3. The CDC assigns an AIDS diagnosis when a person is afflicted with or more rare infections, such as *Pneumocystis pneumonia* or Kaposi's Sarcoma, and/or has less than a 9400 T-helper lymphocyte count. The T-helper cells are counted to determine the extent of HIV infection, because HIV cripples a human immune system by attacking the T-helper cells. For the August, 1987 CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome, see E. NICHOLS, *supra* note 13, at 278-90.

Bristol-Myers, the sponsor of ddI, is requiring physicians to provide considerable data on participants in the ddI Treatment IND protocol.¹³³ This data includes laboratory evaluations every seven to ten days during the first two months of ddI therapy.¹³⁴ The treating physician must report adverse effects of any severity noted during this period to Bristol-Myers by telephone.¹³⁵ If the participant decides to continue on the drug after the first two months, follow-up laboratory evaluations and adverse experience report forms must be submitted every ten days.¹³⁶ Bristol-Myers intends to use the laboratory data from this protocol to enhance data issuing from phase II and phase III trials.¹³⁷ Physicians participating in these trials believe such data will be very helpful in assessing ddI's efficacy.¹³⁸

c. The Open Label Study Regimen

The Open Label Study Regimen, along with Treatment IND protocol, is one of two alternative methodologies presently built into nationwide ddI protocols. The Open Label Study Regimen is designed for patients who are experiencing significant deterioration despite AZT treatment or who are not eligible to enter into phase II clinical trials.¹³⁹ Bristol-Myers intends to gather data about ddI using both double blind placebo studies and the Open Label Study Regimen.¹⁴⁰

The Open Label Study Regimen makes ddI available to PWAs who are "clinically deteriorating" on AZT.¹⁴¹ Participants must have a diagnosis of AIDS that conforms to CDC criteria, and their health status must indicate serious decline as evidenced by certain symptoms.¹⁴²

Bristol-Myers is requiring physicians to provide data on participants in the Open Label Study Regimen as well, including laboratory evaluations.¹⁴³ As in the ddI Treatment IND protocol, treating physicians must report to Bristol-Myers, by telephone, any adverse effects noted during the test period.¹⁴⁴ If the participant decides to continue on the drug after the first two months, follow-up laboratory evaluations and ad-

133. Hafs, *supra* note 129, at 3.

134. *Id.*

135. *Id.*

136. *Id.*

137. Interview with Brian Friedman, M.D., a physician involved with ddI testing through County Community Consortium, a research and informational association in San Francisco, Cal. responsible for many clinical trials of AIDS drugs and treatments (Dec. 12, 1989).

138. *Id.*

139. Hafs, *supra* note 129, at 3.

140. *Id.*

141. *Id.*

142. *Id.*

143. *Id.*

144. *Id.*

verse experience report forms must be submitted every ten days.¹⁴⁵

d. Parallel Tracking

Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease, has proposed Parallel Tracking, which is a system for the early release of drugs.¹⁴⁶ If implemented, this program will make promising drugs available to people who do not qualify for clinical trials or who have not responded positively to currently approved therapies.¹⁴⁷ Drugs under consideration for Parallel Track testing will have three characteristics in common: (1) completion of phase I and pharmacokinetic testing; (2) available data on the drug's interactions with other drugs in common use; and (3) evidence of sufficient efficacy that warrants wider release of the drug.¹⁴⁸ Certain circumstances must also be present for a drug to qualify for release under Parallel Track. Drugs that are designed to treat a disease for which no standard treatment is available will be given priority.¹⁴⁹ Under Parallel Track testing, data is collected and used to test the efficacy of the drug along with data from double blind placebo testing.¹⁵⁰

Physicians treating PWAs believe Parallel Track testing will prove illustrative and reliable as a drug approval method.¹⁵¹ They also believe alternative methodologies would allow more humane and practical testing than the double blind placebo method.¹⁵²

e. The Benefits of New Approaches

Pressure from AIDS activists and a changing philosophy among medical researchers have resulted in the development of new approaches to the testing and distribution of potentially valuable drugs to severely ill patients who in the past had no alternatives.¹⁵³ These approaches circumvent the government's concern about dangerous drugs entering interstate commerce because, under these protocols, orthodox methods for

145. *Id.*

146. Roy, *supra* note 122, at 5; see Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People with AIDS and HIV-Related Disease, 55 Fed. Reg. 20,858 (1990) (proposed Apr. 2, 1990).

147. Roy, *supra* note 122, at 5.

148. *Id.*

149. *Id.*

150. *Id.*

151. Interview with Brian Friedman, M.D., *supra* note 137.

152. *Id.*

153. See Letter from Keith Haring, artist and PWA, who is active in ACT-UP/New York, to supporters of ACT-UP (Autumn 1989); see also Cimon, *FDA Likely to Relax Rules on AIDS Drug*, San Francisco Chron., Sept. 14, 1989, at E9, col. 5; see generally J. JAMES, *supra* note 89, at 277 (David Werdegart, M.D. and San Francisco Director of Health called for faster clinical trials through community-based trials to reduce death from HIV infection.).

testing toxicity remain intact before testing for efficacy begins.¹⁵⁴ Thus, dangerous drugs would be eliminated systematically from these alternative protocols.

Alternative methods for testing new drugs may also reap greater data concerning the application of the drug in various demographic populations.¹⁵⁵ Data collected from a broader spectrum can be assessed and evaluated according to each participant's quality of health. The double blind placebo method requires that participants be screened according to specific narrow criteria.¹⁵⁶ Thus, data collected from double blind placebo tests represents a much smaller field of efficacy.¹⁵⁷ Collecting data from a broader field of participants could result in an informational windfall.

Concern with uncontrolled variables, such as the prior use of another drug or the placebo effect, may be quelled by compiling detailed medical history data from each patient who receives a drug. Were drug approval studies open to more individuals, PWAs would be more honest about their past medical history. Often, PWAs must lie about their medical history to qualify for double blind placebo studies.¹⁵⁸ Data collected under alternative methodologies could be compared across the broad spectrum of participants to analyze the effects of the proposed drug.

To safeguard patients from the risk of receiving a placebo, alternative methodologies could install baseline data from deceased patients who were not treated with the drug in the past.¹⁵⁹ Concern with the placebo effect—the psychologically enhanced effects of receiving a drug¹⁶⁰—may be met with a system of distribution that imposes a rigid standard for physicians who wish to prescribe the drug to their patients. To minimize the placebo effect, physicians could be trained to warn the patient that the drug promises no therapeutic potential, and that it is purely experimental and thus without any proven merit. Such training must be developed and implemented by experts in psychological testing and placebo effect. PWAs do compose a well-informed class, keeping one another educated as to effective treatments. Gossip as to the efficacy of a drug is bound to develop, enhancing the potential for a placebo effect. This, however, also occurs in the context of a double blind placebo study. It is unlikely that such interaction in the alternative context would affect test results any more than in the placebo context. Furthermore, gossip as

154. See *supra* notes 123, 139, & 150 and accompanying text.

155. TREATMENT DECISIONS, *supra* note 16, at 59-60; Long, *supra* note 71.

156. TREATMENT DECISIONS, *supra* note 16, at 59-60; J. JAMES, *supra* note 89, at 380-81 (some trials have such impractical entry criteria that it takes months to recruit even a single patient).

157. TREATMENT DECISIONS, *supra* note 16, at 59-60.

158. *Id.*

159. See *supra* notes 116 & 133 and accompanying text.

160. TREATMENT DECISIONS, *supra* note 16, at 59-60.

to the efficacy of a drug will grow only as the drug proves itself effective. The possibility of a riot of placebo effect occurring during an alternative test is unlikely if a new drug is patently ineffective against HIV, and PWAs are dying in spite of the drug they are receiving.

C. Factor Three: Government's Interest in Substituting Another Procedure for Testing Drugs is Enhanced

The final factor to be considered in a *Mathews v. Eldridge* challenge is the government's interest in alternative procedures. "[I]n a world of limited resources, society cannot afford wholly to ignore interests other than those of the individual asserting a denial of 'life, liberty or property' . . ." ¹⁶¹ To protect the due process rights of PWAs, the FDA must abandon its use of the double blind placebo study to approve new drugs and substitute an alternative methodology. The additional cost to the government for a substitute procedural safeguard would be minimal. Although the FDA would be required to find experts who could assess the data submitted by the pharmaceutical companies using alternative methodologies, the cost of these experts should be no more than the FDA currently shoulders in procuring experts to assess double blind placebo studies. Each new drug must be approved according to a tailored plan or protocol. Each protocol must be submitted to the FDA by the pharmaceutical company before trials may begin. ¹⁶² Experts hired to assess the data could develop the individual protocols, wedding their expertise to the specifics of the drug approval plan. Although these proposed substitute procedures would require some development, the drug manufacturer would gladly carry additional costs in the short term—then pass the additional costs on to consumers after FDA approval of the drug. Most drug companies are willing to shoulder additional costs because they want to market their product in interstate commerce as quickly as possible. ¹⁶³ Considerable litigation evinces the industry's frustration with present protocols and its willingness to underwrite and finance alternative methods. ¹⁶⁴

161. L. TRIBE, *supra* note 43, at 715.

162. 21 C.F.R. § 312.23(a)(6) (1987).

163. Bristol-Myers is distributing dDI free to those eligible under Treatment IND and Open Label Study Regimen. Hafs, *supra* note 129, at 3.

164. See, e.g., *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 609 (1973) (FDA may deny the new drug application for Lutrexin on grounds that the drug was not within the grandfather clause of the FDCA); *Edison Pharmaceutical Co. v. FDA*, 600 F.2d 831, 838-39 (D.C. Cir. 1979) (evidence supported the FDA's conclusion that double blind testing of the new drug ethically could be performed on noncardiac patients and was necessary before the drug could be administered to cardiac patients); *Cooper Laboratories, Inc. v. Commissioner, FDA*, 501 F.2d 772 (D.C. Cir. 1974) (affidavits stating that particular disease for which drug was marketed as treatment was hard to diagnose, ran variable course, and caused pain did not create factual question requiring FDA to conduct hearing as to whether testimonials of experienced physicians, rather than controlled studies, should be recognized as substantial evidence

The proposed change in procedure actually strengthens the government's protection of the public health and welfare. The FDCA is "designed to protect [the] public as a whole by keeping dangerous and deleterious products from reaching [the] uninformed consumer."¹⁶⁵ Alternative methods of testing retain orthodox procedures for ascertaining toxicity and assure the new drug's safety before distributing it to a wider spectrum of patients.¹⁶⁶ Thus, the government's interest in assuring safety would remain paramount in the alternative procedures for approving new drugs. Accordingly, the purpose of the FDCA would be met by alternative methods of testing.

Wider distribution of unapproved drugs would enhance the government's protection of the public health and welfare by prolonging the lives of hundreds of thousands who are afflicted with HIV infection. Protection of the public welfare may also be enhanced by alternative testing methodologies because the compiled data generated by these testing methodologies may be more comprehensive than that gathered by the double blind placebo method.¹⁶⁷ Alternative testing methods produce broad based data, determining efficacy as the new drug is administered to a variety of persons afflicted with HIV. Such data would be collected after the drug has been proven safe. Additionally, side effects of the drug which occur with some rarity will be discovered promptly, because alternative procedures would gather greater data from a more diverse pool of participants.¹⁶⁸

Prolonged health and life for many PWAs could also result in a lightened patient load for private and public hospitals that are presently experiencing a health care capacity crisis due to the epidemic proportion of HIV patients.¹⁶⁹ Hospitals nationwide are buckling under the load of HIV patients seeking treatment.¹⁷⁰ If this load were lightened, these facilities could provide better care to catastrophically ill people, be they PWAs or those with non-HIV ailments.

As potentially helpful drugs become more available, PWAs may not be as susceptible to abandoning faith in Western medicine for esoteric,

of drug's efficacy); *Edison Pharmaceutical Co. v. FDA*, 513 F.2d 1063 (D.C. Cir. 1973) (FDA is required to hold hearing when there is factual question as to whether double blind tests for new drug approval were too dangerous to perform).

165. *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 704, 60 Cal. Rptr. 398, 409 (1967).

166. See *supra* note 157 and accompanying text.

167. See *supra* notes 158-63 and accompanying text.

168. *Id.*

169. E. NICHOLS, *supra* note 13, at 200, 259-73; Landers & Seage, *Medical Care of AIDS in New England*, in *THE AIDS EPIDEMIC: PRIVATE RIGHTS AND PUBLIC INTEREST*, *supra* note 13, at 257-72; Green, Wintfeld, Singer & Schulman, *AIDS and New England Hospitals*, in *THE AIDS EPIDEMIC: PRIVATE RIGHTS AND PUBLIC INTEREST*, *supra* note 13, at 273-83.

170. E. NICHOLS, *supra* note 13, at 200, 259-73.

unproven Eastern or New Age therapies.¹⁷¹

The development of alternative testing methods for AIDS drugs paves the way for use of such methods in other contexts.¹⁷² While AIDS poses an immediate threat, other diseases that may be equally dangerous to a great many people exist or may be on the horizon. Development and implementation of alternative testing methods in the AIDS context will allow medical science and the FDA to expedite palliative treatments for a variety of other fatal illnesses. Use of alternative testing protocols in the AIDS context will furnish scientists with data with which they may tailor testing methods to the diseases and new drugs they may confront. Alternative testing methods may be used in the AIDS context to provide a valuable "trial run."¹⁷³

IV. Conclusion

AIDS is a disease that poses a serious threat to public health both in the United States and worldwide. Its danger is not confined to its lethal efficiency. Much of what makes AIDS problematic is medical science's embryonic understanding of viruses generally and retroviruses specifically. Thus, HIV infection is presently treated with the few drugs and therapies available in the marketplace. Although these treatments have proven to be helpful, many PWAs are unable to use these FDA approved treatments for very long, if at all.

Drugs are being developed to block the progress of AIDS; these drugs, however, are slow to enter the marketplace. The FDA's method for approving new drugs bottlenecks the dissemination of newly developed drugs that are effective in the treatment of AIDS. The double blind placebo study is the main offender in the FDA's approval procedures. A double blind placebo study may take twelve years from development to completion, during which time hundreds of thousands will die of AIDS. The FDA should abandon its use of double blind placebo studies where a great loss of life is inevitable.

The Court should recognize a PWA's due process right of access to new, potentially life-extending drugs. Under the *Mathews v. Eldridge*¹⁷⁴ analysis, PWAs can demonstrate their protected interests in life and liberty and that they are denied these interests by the FDA's use of double blind placebo studies to approve new drugs. Under *Mathews*, the PWA can also produce alternative methods for approving new drugs—each of

171. See TREATMENT DECISIONS, *supra* note 16, at 50; see also E. NICHOLS, *supra* note 13, at 198-99 (PWAs are manufacturing their own remedies in kitchens and basements).

172. TREATMENT DECISIONS, *supra* note 16, at 75-76.

173. For an insightful and probative essay on the problems with the FDA drug approval process in the AIDS context, see Pier, *The Emperor Has No Clothes: Notes on AIDS Drug Testing and Access*, in J. JAMES, *supra* note 89, at 354-57.

174. 424 U.S. 319 (1974).

which functions to disseminate new drugs more quickly and more humanely. These new methods are not substantially more expensive to implement, and rapid dissemination of helpful drugs would lessen the burden on American hospitals, which are buckling under the weight of the epidemic. Thus, the FDA should loosen its strict adherence to the double blind placebo method to prevent the risk of an erroneous deprivation of PWAs' interests in life and liberty. If the FDA were to do so, either on its own initiative or by court order, hundreds of thousands of lives may be saved.¹⁷⁵

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175. The statistics provided in this Essay were current at the time of writing. By the time of publication, however, the number of Americans diagnosed with AIDS had increased to 161,073 and the number of Americans who have died has increased to 100,813. Telephone interview with Centers for Disease Control (January 30, 1991)(statistics as of December 31, 1990); see *supra* notes 9 & 10 and accompanying text.

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